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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/739,014 07/31/91 YAMAMOTO

J 2307U-237-3/

EXAMINER

BARND, D

ART UNIT

PAPER NUMBER

1813

5

DATE MAILED: 01/22/92

JAMES M. HESLIN
TOWNSEND AND TOWNSEND
ONE MARKET PLAZA
STEUART STREET TOWER
SAN FRANCISCO, CA 94105

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12/9/91 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice re Patent Drawing, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☒ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ _____

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Part II SUMMARY OF ACTION

1. ☒ Claims 1-13 are pending in the application.

Of the above, claims 11-13 are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-10 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received

☐ been filed in parent application serial no. _____

SN 07/739,014
Art Unit 1813

15. Applicant is required to update the status of the parent application 07/618,030 (now Patent No. 5,037,753) included in the cross-reference to related applications made on page 1, line 1 of the specification.

16. Applicant's election with traverse of the invention of Group I, claims 1-10 (drawn to a FIV vaccine and a method of using such a vaccine in vivo), in Paper No. 4, is acknowledged. The traversal is on the grounds that simultaneous examination of the inventions of Groups I and II would not present an undue burden on the Examiner. This is not found persuasive because the invention of Group II (cell lines chronically infected with FIV) and the invention of Group I (a vaccine comprising FIV-infected cell lines) have acquired a separate status in the art as shown by their different classification, and examination of the invention of Group I requires searching of subclasses not required for examination of the invention of Group II. Additionally, the vaccine composition of Group I comprises immunogens other than the virus-infected cell lines of Group II, and the infected cell lines of Group II may not all be useful in the vaccine composition of Group I. The requirement is still deemed to be proper and is therefore made FINAL. Claims 11-13 are withdrawn from further consideration by the Examiner 37 CFR 1.142(b) as being drawn to a non-elected invention.

17. The disclosure is objected to because of the following informalities:

a) The description of Figures 2A-F appears to improperly describe the order of the Figures (e.g. CD4 and pan T cell FACS profiles appear to be inverted with regard to their description).

b) Reference to Table 1 has been made in several instances where it appears that reference to Table 2 was intended (e.g. p. 36, line 37; p.41, line 36).

c) Reference to Figures 8A and 8 B has been made on p. 9, lines 10 and 11, where it appears that reference to Figures 9A and 9B was intended.

Appropriate correction is required.

18. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

19. Claims 1-10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3-11 of copending application Serial No. 07/726,061. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

20. Claims 1-10 are rejected under 35 U.S.C. 101 because the invention as disclosed lacks utility. No evidence is provided in the specification that the disclosed vaccine will protect against FIV strains heterologous to that used for vaccination. The FIV envelope protein is similar to the HIV envelope protein in that its amino acid sequence is divergent among different virus isolates (see Jarrett et al., p. S163). The hypervariability present in the envelope protein of HIV isolates obtained either from a single individual or from different individuals is believed to be a major stumbling block in developing a vaccine useful against all strains of HIV (see Berzofsky et al., p. 453). Because the FIV envelope protein is believed to be essential for vaccine-induced protection (see specification, p. 42), it is unclear that the vaccine disclosed will provide adequate protection against all strains of FIV an animal might be expected to encounter.

21. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and use the invention, i.e. failing to provide an enabling disclosure. The specification is not enabled for the production and use of the claimed vaccine because the utility of the invention has not been proven, for the same reasons outlined in the rejection under 35 U.S.C. 101 above.

22. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action:

A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

A person shall be entitled to a patent unless (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

24. Claims 4 and 10 are rejected under 35 U.S.C 102(a) as being anticipated by Jarrett et al.. Jarrett et al. disclose a vaccine composition comprising chemically-inactivated whole cells derived from an FIV-infected cell line, and a method of using such a composition to vaccinate cats (see p. S164).

25. Claims 1-10 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending application Serial No. 07/726,061. Copending application Serial No. 07/726,061 has one common inventor and a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. (e) is based upon a presumption of future patenting of the conflicting copending application.

This provisional rejection under section 102(e) might be overcome either by a showing under 37 CFR 1.132 that any unclaimed invention disclosed in the copending application was derived from the inventor of this application and is thus not the invention "by another", or by a showing of a date of invention of any unclaimed subject matter prior to the effective U.S. filing date of the copending application.

26. Claims 1-10 are directed to the same invention as that of claims 3-11 of commonly assigned application Serial No. 07/726,061. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the Patent and Trademark Office normally will not institute an interference between application or a patent and an application of common ownership (see MPEP 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) and (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of the application.

27. No claims are allowable.

28. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

29. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4227.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna L. Barnd whose telephone number is (703) 308-3908. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

December 23, 1991

Donna L. Barnd, Ph.D.



CHRISTINE NUCKER
PRIMARY EXAMINER
ART UNIT 1813